

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: BENNEKER et al.  
Title: ***4-PHENYLPIPERIDINE COMPOUNDS***  
Appl. No.: 09/200,743  
Filing Date: 11/30/1998  
Examiner: Celia C. Chang  
Art Unit: 1625  
Confirmation Number: 9739

**RESPONSE UNDER 37 C.F.R. § 1.111 & 1.114**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Claim 31 is pending in the application and was allowed. The issue fee was paid October 1, 2008. A Petition to Withdraw under 37 CFR § 1.313(c)(2) is filed concurrently, to permit Applicant to file an RCE and IDS to make of record an opinion by the United Kingdom House of Lords of Appeal ("the UK opinion") that discusses a non-U.S. application related to the present application. A Rule 132 Declaration by Jose Sintas, Ph.D., an employee of Noven Pharmaceuticals, Inc., which is a corporate entity related to Noven Therapeutics, Inc., the assignee of the captioned application, also is submitted for the Examiner's consideration.

The UK opinion concerns the unpatentability of a Smithkline Beecham UK patent in view of a Synthon patent application that is related to this U.S. application. The UK opinion characterizes in general terms the activities of two chemists who sought to make crystals of paroxetine mesylate ("PM") according to the procedure described in the Synthon application.

*See, e.g.*, UK opinion, page 6, ¶15. The UK opinion states that crystals of PM eventually produced by the chemists did not “have the IR spectrum predicted by Synthon in Table 1,” but “instead had the spectrum described in the [Smithkline Beecham patent].” *See, e.g.*, UK opinion, page 6, ¶15. The UK opinion states further that the “IR spectrum in Table 1 of [Synthon’s] application was the result of a mistaken reading in their own laboratory.” *See, e.g.*, UK opinion, page 7, ¶16.

Applicant understands that the UK opinion may raise questions surrounding the IR data recited in allowed claim 31 of the U.S. application. However, the Dr. Sintas’ Rule 132 Declaration evidences that the recited IR data correctly characterize crystals of paroxetine mesylate (“PM”).

As Dr. Sintas notes in ¶5 of his Declaration, “[c]rystalline PM is an active pharmaceutical ingredient (“API”) that is produced for Noven by several different manufacturers.” Dr. Sintas attests that “[t]he IR spectra of crystalline PM obtained from different API manufacturers are identical, and they correspond to the IR peaks disclosed and claimed in the U.S. application.” Sintas Declaration, ¶5. As Dr. Sintas explains in ¶8 of his Declaration, “the IR spectra [of the API batches] contain bands that are characteristic of structural features of PM,” and “confirm that the IR spectra are consistent with what someone skilled in the art would expect for PM.”

Dr. Sintas considered whether the IR spectra of the API batches correspond to the IR data disclosed and claimed in this application, and concluded that they do. *See, e.g.*, Sintas Declaration, ¶12, 16.

Dr. Sintas also examined a copy of an IR spectrum of crystalline PM that Smithkline Beecham submitted during prosecution of the European patent (EP 0970955) related to the UK patent at issue in the UK opinion. Sintas Declaration, ¶13 (The IR spectrum (“the SKB spectrum”) was submitted to the European Patent Office (“EPO”) as part of an affidavit by Mr. Ian Robert Lynch, and is available from the EPO website.) Dr. Sintas concluded that “the SKB spectrum . . . characterizes the same crystal form of crystalline PM as the IR spectra [of the Noven API batches].” Sintas Declaration, ¶14. Dr. Sintas also concluded “that the

claimed IR peaks [of allowed claim 31] characterize the same crystal form of crystalline PM as the SKB spectrum.” Sintas Declaration, ¶15.

Thus, Dr. Sintas’ Declaration evidences that the “application discloses and claims IR peaks that characterize the same crystal form of crystalline PM as is used in Noven’s commercial crystalline PM products and that was the basis of Smithkline Beecham’s IR spectrum.” Sintas Declaration, ¶16.

Applicant believes that claim 31 remains in condition for allowance, and an early notice to that effect is earnestly solicited. Should there be any questions regarding this submission, or should any issue remain, the Examiner is urged to contact the undersigned at the telephone number set forth below to expedite prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required for this application, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 6, 2009

By Courtenay C. Brinckerhoff

FOLEY & LARDNER LLP  
Customer Number: 22428  
Telephone: (202) 295-4094  
Facsimile: (202) 672-5399

Courtenay C. Brinckerhoff  
Attorney for Applicant  
Registration No. 37,288